



NDA 20-329/S-006

Pfizer Pharmaceuticals Group
Attention: Michelle G. Campbell, RPh
Director, Worldwide Regulatory Strategy
235 E. 42nd Street 150/7/12
New York, NY 10017

06 SEP 2001

Dear Ms. Campbell:

Please refer to your supplemental new drug application dated December 20, 1999, received December 21, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Glucotrol XL (glipizide) Extended Release Tablets.

We acknowledge receipt of your submission dated May 24, 2001, which constituted a complete response to our May 14, 2001 action letter.

This supplemental new drug application provides for a patient package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

Under the subheading, "Other Side Effects", please correct the statement to read, "While it has never been reported with GLUCOTROL XL, another similar type of diabetes medicine has been linked to a higher risk of heart attacks."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (patient package insert submitted May 24, 2001). These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-329/S-006." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you

submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call James T. Cross , at 301-480-8174.

Sincerely,

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research